



Complete Summary

GUIDELINE TITLE

PET imaging in colorectal cancer: recommendations.

BIBLIOGRAPHIC SOURCE(S)

Chan K, Welch S, Walker-Dilks C. PET imaging in colorectal cancer: recommendations. Toronto (ON): Cancer Care Ontario (CCO); 2009 Jan 19. 33 p. (Recommendation report - PET; no. 1). [37 references]

GUIDELINE STATUS

This is the current release of the guideline.

The EVIDENCE-BASED SERIES report, initially the full original Guideline, over time will expand to contain new information emerging from their reviewing and updating activities.

Please visit the [Cancer Care Ontario Web site](#) for details on any new evidence that has emerged and implications to the guidelines.

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SCOPE

DISEASE/CONDITION(S)

Colorectal cancer

GUIDELINE CATEGORY

Diagnosis
Evaluation

Management
Technology Assessment

CLINICAL SPECIALTY

Colon and Rectal Surgery
Gastroenterology
Nuclear Medicine
Oncology
Radiation Oncology
Radiology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To evaluate:

- What benefit to clinical management does positron emission tomography (PET) or positron emission tomography/computed tomography (PET/CT) contribute to the diagnosis or staging of colorectal cancer?
- What benefit to clinical management does PET or PET/CT contribute to the assessment of treatment response for colorectal cancer?
- What benefit to clinical management does PET or PET/CT contribute when the recurrence of colorectal cancer is suspected but not proven?
- What benefit to clinical management does PET or PET/CT contribute to restaging at the time of the documented recurrence for colorectal cancer?
- What is the role of PET when a solitary metastasis is identified at the time of recurrence and a metastasectomy is being contemplated?

TARGET POPULATION

Patients with colorectal cancer

INTERVENTIONS AND PRACTICES CONSIDERED

1. Positron emission tomography (PET)
2. Positron emission tomography/computed tomography (PET/CT)

MAJOR OUTCOMES CONSIDERED

Sensitivity and specificity of positron emission tomography (PET) and positron emission tomography/computed tomography (PET/CT)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Systematic Review

A systematic review of the published literature was undertaken (see details below). This was conducted by two clinical lead authors, nominated by the Program in Evidence-Based Care (PEBC) Gastrointestinal Disease Site Group (GI DSG) and a PEBC methodologist. The systematic review served as the evidentiary foundation for a set of draft recommendations developed by this team.

Literature Search

A scoping review undertaken by the PEBC methodologist to identify any existing systematic reviews on positron emission tomography (PET) imaging in the cancers of interest, yielded such a review. The U.K. Health Technology Assessment (HTA) systematic review (referred to as the HTA review from this point forward) evaluated the effectiveness of fludeoxy-glucose (FDG) PET imaging in several selected cancers, including colorectal. The document included systematic reviews and individual primary studies dating from 2000 to August 2005. Because the HTA review sufficiently covered the questions and methodologies of interest to this recommendation report, its results were used for the evidence base from 2000 to August 2005, and its search strategies were performed in MEDLINE and EMBASE to update the literature to June 2008. The update strategies for MEDLINE and EMBASE are in Appendices 1 and 2 in the original guideline document, respectively.

Study Selection Criteria

All systematic reviews and primary studies in the HTA review that addressed the questions of interest in this recommendation report (diagnosis, staging, treatment response, recurrence, and restaging) were included. The inclusion criteria of the HTA review were employed to select systematic reviews and primary studies identified in the update search.

The inclusion criteria for systematic reviews included in the HTA review and used in the update were:

- Dedicated to FDG PET in the selected cancers in humans
- Contained evidence related to diagnostic accuracy, change in patient management, clinical outcomes, or treatment response

The inclusion criteria for primary studies included in the HTA review and used in the update were:

- Prospective clinical study of dedicated FDG PET in a single cancer of interest
- Study published after the search date of a robust systematic review covering that cancer management decision

- Study published as a full article in a peer-reviewed journal
- Study reported evidence related to diagnostic accuracy, change in patient management, or clinical outcomes
- Study included ≥ 12 patients with the cancer of interest
- Study used a suitable reference standard (pathological confirmation and clinical follow-up) when appropriate

The citations and abstracts from the update searches were reviewed by the PEBC research coordinator and marked as relevant or not relevant, according to the inclusion criteria from the HTA review, and were classified by disease site. The research coordinator and the clinical lead for each Disease Site Group (DSG) reviewed the relevant citations and full text of the articles for final decision on inclusion.

NUMBER OF SOURCE DOCUMENTS

The Health Technology Assessment (HTA) review results for colorectal cancer included three systematic reviews and 24 primary studies. The 2005 to 2008 update included six systematic reviews and 19 primary studies.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Synthesizing the Evidence

The Health Technology Assessment (HTA) review did not pool individual studies. Data were extracted into separate tables for systematic reviews and primary studies for each type of management decision. The same approach was used for data extraction for the evidence from August 2005 to June 2008. Full text and data extractions of the studies from the update search were provided to the clinical lead authors to aid in the formulation of the recommendations. Telephone conferences and email correspondence between the clinical leads and the Program in Evidence-Based Care (PEBC) methodologist took place to clarify details and answer questions.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Consensus by the Program in Evidence-Based Care (PEBC) Gastrointestinal Disease Site Group (GI DSG)

The draft recommendations were refined during a DSG teleconference. The GI DSG is comprised of medical and radiation oncologists and surgeons and is supported by a PEBC research methodologist.

DSG Consensus Process

The clinical lead authors wrote summaries of the key evidence, draft recommendations, and qualifying statements for the questions pertaining to diagnosis/staging, assessment of treatment response, and recurrence/restaging. Due to the special interest of the GI DSG, a recommendation was also drafted pertaining to the use of positron emission tomography (PET) in colorectal cancer liver metastasis. The ensuing documents were circulated to all members of the GI DSG and discussed during a teleconference. The recommendations that were generated during this process are referred to below as the DRAFT DSG Recommendations. The intent of these recommendations was to guide discussion at the consensus meeting.

Provincial PET Imaging Consensus Meeting

The draft recommendations were vetted at a larger provincial PET imaging consensus meeting co-hosted by Cancer Care Ontario and the Provincial PET Steering Committee. The meeting was facilitated and supported by members of the PEBC team. Participants included representatives of the PEBC DSGs, other clinical experts in the areas of nuclear and diagnostic medicine, members of the Cancer Care Ontario clinical leadership team, and representatives from the Ontario PET Steering Committee and the Ontario Health Technology Assessment (HTA) Committee.

Provincial Consensus Process

The consensus meeting on 19 September 2008 was conducted as follows:

- Consensus meeting participants sat at tables specifically set up to discuss a particular disease site (colorectal, esophageal, head & neck, and melanoma). The colorectal table held the two clinical leads and any other GI DSG members attending, in addition to other invited health professionals.
- The recommendations and summary of key evidence drafted by the clinical leads and refined and confirmed by the GI DSG were presented by the clinical leads to the group at the colorectal table.
- During small-group discussion at the colorectal table in the morning and discussion among the entire consensus meeting participants in the afternoon, the recommendations underwent further refinement and modification. The attendees voted on the revised recommendations to indicate their extent of agreement on a scale from 1 to 9 (1 indicating strong agreement, 5 indicating no agreement or disagreement, and 9 indicating strong disagreement).

After the consensus meeting, the exact wording of the recommendations was slightly modified for consistency with the recommendations resulting from the other disease discussions. These modifications included using emphatic, unambiguous language (i.e., *PET is recommended*) and removing the need to distinguish between PET and PET/CT. It was made clear at the consensus meeting that PET imaging alone is being phased out and PET/CT imaging is the current standard. Thus, the term PET is used to cover PET and PET/CT imaging.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnosis/Staging

- The routine use of positron emission tomography (PET) is not recommended for the diagnosis or staging of clinical Stage I-III colorectal cancers.
- PET is recommended for determining management and prognosis if conventional imaging is equivocal for the presence of metastatic disease.

Assessment of Treatment Response

The routine use of PET is not recommended for the measurement of treatment response in locally advanced rectal cancer before and after preoperative chemotherapy.

Recurrence/Restaging

- PET is not recommended for routine surveillance in patients with colorectal cancer treated with curative surgery at high risk for recurrence.
- PET is recommended to determine site of recurrence in the setting of rising carcinoembryonic antigen (CEA) when conventional workup fails to unequivocally identify metastatic disease.

Liver Metastasis

PET is recommended in the preoperative assessment of colorectal cancer liver metastasis prior to surgical resection.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

These recommendations are based on an evidentiary foundation consisting of one recent high-quality U.K. Health Technology Assessment systematic review that included systematic review and primary study literature for the period from 2000 to August 2005 and an update of that systematic review undertaken to retrieve the same level of evidence for the period from August 2005 to June 2008.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of positron emission tomography (PET) and positron emission tomography/computed tomography (PET/CT) imaging in patients with colorectal cancer.

Refer to the original guideline document for key evidence supporting the recommendations for use.

POTENTIAL HARMS

False positive and false negative results, which may lead to overtreatment or undertreatment

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Diagnosis/Staging

- Some studies evaluated the diagnostic performance of positron emission tomography (PET) or positron emission tomography/computed tomography (PET/CT) with respect to each metastatic site/organ/lesion, while some evaluated it with respect to the M-staging of each patient. It would appear that studies that analyzed results based on each site/organ/lesion showed a better performance of PET or PET/CT, while studies that analyzed results based on the overall M-staging of patients did not show an obvious improvement in performance of PET or PET/CT. As solitary or oligo-metastasis

is not a very common presentation in the initial diagnosis of colorectal cancer, it would be unlikely that PET or PET/CT would detect such a situation when CT missed it, if the objective was to change M-staging and management of these patients. However, in patients who already have suspicious or confirmed metastasis based on CT, it is quite possible that PET or PET/CT could detect further metastases in other sites/organs that were not conclusively detected by CT alone. This will inflate the diagnostic performance of PET or PET/CT if analysis was based on sites/organs/lesions instead of overall M-staging of each patient. This factor may be important when making recommendations for early-stage disease versus metastatic disease.

- On the other hand, for patients who already have what appears to be solitary or oligo-metastases on CT only, and who are potential candidates for resection, and given that the possibility of further metastasis in other sites/organs is not low, PET or PET/CT may assist in the decision making of resection with curative intent by helping to assess the extent of metastasis. Studies that analyzed the diagnostic performance of PET or PET/CT, with respect to sites/organs/lesions, provided evidence to support this approach. Therefore, there may be a role for the use of PET or PET/CT when conventional imaging raises suspicion of the presence of potentially resectable metastatic disease, and patients are potential candidates to undergo such surgery. The incremental benefit of PET or PET/CT over magnetic resonance imaging (MRI) of the liver is unclear in such populations as none of the studies included the routine use of MRI as part of conventional imaging.
- Most studies that showed PET or PET/CT changed the management of a significant proportion of patients included a relatively large number with stage IV disease (up to 46% of patients). Studies that included a relatively small proportion of stage IV patients did not appear to show a significant benefit or change in the patient management plan with PET or PET/CT. Some of those changes in management involved the detection of a larger than expected volume of disease in the liver or extrahepatic metastasis by PET or PET/CT in patients originally diagnosed with low-volume resectable liver metastasis by conventional imaging.
- Most studies that compared PET or PET/CT with conventional imaging were done in the time period when multidetector CT (MDCT) was not yet widely available. The only study that clearly stated that MDCT was used did not show clinically relevant superiority of PET in addition to MDCT). As MDCT is being used routinely in most of the cancer centres and hospitals in Ontario, the incremental benefit of PET or PET/CT for routine staging of colorectal cancers remains to be established.
- While some studies reported the numerical comparisons of diagnostic performance between PET (or PET/CT) and conventional imaging, few studies tested whether the numerical differences observed were statistically significant or not.
- It is unclear whether PET or PET/CT leads to improvement in survival or simply results in stage migration. Nonetheless, many practitioners may accept that more accurate staging will lead to a better choice of treatment plan, thereby avoiding overtreatment and sparing patients the unnecessary risk or side effects of therapy or avoiding undertreatment when patients might otherwise benefit from aggressive curative-intent therapy.
- There are very few studies that evaluated rectal cancer and colon cancer separately. The current limited evidence did not obviously suggest or refute that PET or PET/CT significantly changed management in patients with non-metastatic rectal cancer. However, some studies seemed to suggest that PET

or PET/CT has better N-stage accuracy than CT. It is unclear how PET or PET/CT compares with MRI or trans-rectal ultrasound (TRUS) with respect to N-staging. There may be a role of PET/CT with respect to N-staging in the decision making for patients with non-metastatic rectal cancer who may be candidates for preoperative chemoradiotherapy.

Liver Metastasis

- Despite the change in management reported in these nonrandomized studies, the possibility cannot be ruled out that factors other than PET results were involved in that change.
- In the evaluation of patients potentially eligible for curative resection of colorectal cancer liver metastasis, a diagnostic CT is necessary in addition to PET/CT to provide information on hepatic vasculature and anatomy.
- The sensitivity of PET for detecting metastases decreases following neoadjuvant chemotherapy in patients with colorectal cancer liver metastasis. PET is less sensitive than CT for detecting metastases following neoadjuvant chemotherapy. If PET is to be used for staging purposes, it should be performed before and after neoadjuvant chemotherapy.

Disclaimer

Care has been taken in the preparation of the information contained in this report. Nonetheless, any person seeking to apply or consult the report is expected to use independent medical judgment in the context of individual clinical circumstances or seek out the supervision of a qualified clinician. Cancer Care Ontario makes no representation or guarantees of any kind whatsoever regarding the report content or use or application and disclaims any responsibility for its application or use in any way.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2009 Jan 19

GUIDELINE DEVELOPER(S)

Program in Evidence-based Care - State/Local Government Agency [Non-U.S.]

GUIDELINE DEVELOPER COMMENT

The Program in Evidence-Based Care (PEBC) is a Province of Ontario initiative sponsored by Cancer Care Ontario and the Ontario Ministry of Health and Long-Term Care.

SOURCE(S) OF FUNDING

Cancer Care Ontario
Ontario Ministry of Health and Long-Term Care

GUIDELINE COMMITTEE

Gastrointestinal Disease Site Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

For a current list of past and present members, please see the [Cancer Care Ontario Web site](#).

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Members of the Gastrointestinal Disease Site Group (GI DSG) involved in the development of this systematic review and practice guideline were polled for potential conflicts of interest. No conflicts were declared.

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [Cancer Care Ontario Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Browman GP, Levine MN, Mohide EA, Hayward RSA, Pritchard KI, Gafni A, et al. The practice guidelines development cycle: a conceptual tool for practice guidelines development and implementation. J Clin Oncol 1995;13(2):502-12.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI Institute on April 26, 2010.

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